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Quality of Care and Outcomes Assessment

THE LEARNING CURVE FOR MEDICAL DEVICES: EXPERIENCE WITH VASCULAR CLOSURE DEVICES IN MASSACHUSETTS

Moderated Poster Contributions
Poster Sessions, Expo North
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Session Title: Enhancing Value in Coronary Intervention and Myocardial Infarction Care
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Background: Clinical outcomes following medical device deployment depend on device design, patient traits, and operator experience. We use propensity score matched patient groups exposed to AngioSeal (AS) or StarClose (SC) vascular closure devices (VCDs) to compare vascular complications related to VCDs to operator experience,

Methods: Patients in the Massachusetts PCI registry were included if they received SC or AS between March 1, 2005 and June 27, 2009, did not receive intra-aortic balloon pump, had only one PCI during admission, and received only one hemostasis method after PCI. The primary outcome was a composite of failed VCD deployment and vascular complications before discharge. Patients were matched by propensity score (13 patient traits and 8 medications). The first 25 VCD deployments were defined as early.

Results: 123 physicians at 23 hospitals performed 6,925 PCIs. The median (maximum) VCD-specific deployment per physician was 58 (382). The primary outcome was observed in 1.9% of PCIs and was similar in each group after matching [SC: 1.8% vs. AS 1.9%, 2,712 matched pairs]. Outcomes were worse for SC than for AS in early (first 25) deployments [SC 2.64% vs AS 2.16%] but better for later (> 25) deployments [1.38% vs. 1.82%]. The rate and magnitude of learning differed between the two devices.

Conclusion: Experience had different effects on outcomes for the SC and AS VCDs. These results can be applied to device regulation and physician training.